# PMOS EXHIBIT 11

## EXHIBIT 19 OF RYAN DIETZ'S DECEMBER 6, 2018 DEPOSITION: HOSPITAL "GUIDELINES" RE EQUITY REFERENCED IN THE BCH POLICY

NOTE: DEFENDANT HAS WAIVED "CONFIDENTIAL" STATUS FOR THIS DOCUMENT

Dietz
EXHIBIT NO. 19
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# Appendix B

Guidelines for Managing Equity Obtained

in the Transfer of Hospital Owned Technology

INTRODUCTION

Children's Hospital increasingly finds that in many cases the most appropriate method to commercialize a technology is to transfer the technology to a young company and to receive stock, stock options, warrants or similar ownership interests (hereinafter "equity" or "stock")! in the company as consideration for the transfer. Taking equity in companies to which the Hospital transfers technology, however, raises serious questions of conflicts of interest. Although the conflicts of interest posed to the Hospital in such arrangements generally are not significantly different from those of the more common industrial relationships. into which the Hospital routinely enters (e.g., sponsored basic research, sponsored clinical trials, and licenses with royalties and milestone payments), there are differences in fact and perception and it is important that the Hospital be particularly sensitive to the potential for such conflicts given the limited experience in such arrangements.

THE DECISION TO ACCEPT EOUITY

This document is designed to offer a context in which issues relating to equity ownership by the Hospital in exchange for technology can be considered. Because of the complexity and significance of the issues involved, and because of the institution's lack of experience in this area, decisions regarding the taking of equity in exchange for Hospital Technology should be reviewed and approved by the Executive Committee of the Board of Trustees of the Hospital. As the Hospital gains experience in this area, other processes may prove to be more appropriate regarding the decision to take equity.

Once a decision is made in a particular case to take equity, the Hospital is committed to oversight and monitoring of the ensuing relationship. This function may be undertaken by the Executive Committee of the Board itself, or the Executive Committee, in its judgment, may designate a Review Committee to carry out this function.

The guidelines contained in this document are just that - guidelines. It is anticipated that the Hospital will learn

through actual experience and will add to, delete or alter these guidelines as appropriate.

1. The intent of these guidelines is to use the term "equity" in the broadest possible fashion. The decision as to what constitutes "equity" in any given situation is reserved to the Executive Committee of the Board of Trustees.

MANAGEMENT OF EQUITY:

How to distribute: Typically, Children's Medical Center Corporation ("CMCC") will be the title and record owner of all equity obtained as a result of the transfer of Hospital-owned technology2. CMCC will have all shareholder rights and will maintain ownership or sell the equity at its discretion, subject to legal restrictions and the considerations set forth in these guidelines. In accordance with the Hospital's intellectual property policy, cash proceeds from the sale of equity will be distributed as follows: 25% to the investigator, 25% to the department; 40% to the General Research Endowment; and 10% to support the Hospital's technology transfer office.

Inventor's option: At the Hospital's discretion, inventors will have the option to obtain direct ownership of equity at the time the license is executed, if permitted by the company, applicable securities law and the conflict of interest policies of the Hospital and Harvard Medical School (HMS). Under these conditions, the Hospital will transfer ownership to the inventor(s) of 25% of the shares of stock received under the license or cause the company to issue the stock directly to the inventor. Thereafter, the inventor will not benefit from the sale of the stock received by the Hospital. Each inventor, in the case of multiple inventors, may make an election separately from the others.

Who will manage the Hospital's share: Any equity obtained by the Hospital pursuant to the transfer of a Hospital-owned technology generally will be managed in the same way all stock is managed and may be sold when deemed appropriate in the sole discretion of the Hospital. In the discretion of the Executive Committee of the Board, however, the equity obtained in any given case may be managed by whatever mechanism the Committee deems appropriate, including but not limited to an independent financial management fund, a blind trust, or the like. In choosing the appropriate equity management mechanism, the Hospital will endeavor to ensure that the designation is consistent with the protection of its academic principles. To this end, the Hospital will take

measures to isolate individuals responsible for equity management from the inventors who have relationships with industry. Further, the Hospital believes that if a decision regarding institutional equity presents a conflict between the objectives of protecting academic principles and making sound financial decisions, the 'p'rotection of academic principles must prevail over the Hospital's opportunity for financial gain.

An inventor may own equity independently from the Hospital: To minimize the possible divergence of the separate interests of the inventor and Hospital, the following will apply. Normally, the Hospital will acquire equity at the time of licensing, and future equity may be received by the Hospital as developmental milestones are achieved by the company. Equity received by the

2. For purposes of this paper the terms "CMCC", "Medical Center", and "Hospital" will be used interchangeably.

Hospital, both upon licensing and as milestones are reached by the company, will be distributed to inventors who elect to receive it, in accordance with the Hospital's intellectual property policy. In addition, at the time of or subsequent to licensing, inventors may contract to perform future services to the company and may be compensated in part by receiving additional equity independent of the equity received by the Hospital, if approved by the Hospital and in compliance with Hospital and applicable HMS policies.

MANAGEMENT OF THE INDUSTRIAL RELATIONSHIP TO AVOID CONFLICT

Sponsored research: The Hospital may participate in research sponsored by a company in which the Hospital owns equity. Inventors who elect to receive equity in a company may not conduct or be involved in research at the Hospital, which is sponsored by that company. Where the Hospital owns the stock and the inventor shares in cash proceeds from a sale of the stock under the Hospital's intellectual property policy, the inventor may conduct and otherwise be involved in research sponsored by the company.

When the Hospital takes equity and also receives sponsored research support from the company issuing the equity, the Hospital will be especially sensitive to the possibility of unduly influencing either (a) the appropriate allocation of institutional resources, or (b) the research direction of the investigator concerned.

Clinical trials: The Hospital may participate in clinical trials sponsored by a company in which the Hospital holds

stock. Any such clinical trial may not be directed by the inventor of the product, which is the subject of the trial. The principal investigator of the clinical study cannot be directly or indirectly supervised by the inventor. It is expected that confirmatory clinical trials (typically Phase II and Phase III studies) will be conducted as a multi-center study and directed by a principal investigator with no affiliation with the Hospital.

In deciding whether to participate in a clinical trial sponsored by a company in which the Hospital owns equity, the Hospital will consider the following and take steps to ensure (1) patient safety (2) validity and integrity of the data generated from the clinical trial (3) that the Hospital's equity interest is disclosed to its institutional review board (IRB) in order that the IRB can determine, among other things, in what manner and to what extent such information should be shared with patients and *others* (4) that inappropriate preferential access to patient populations is not provided to companies in which the Hospital owns equity.

Medical students, residents and post-doctoral fellows ("trainees"): The education and training of students, residents and post-doctoral fellows is one of the primary missions of the Hospital. The participation of trainees in academic research is a key component of such training. In building relationships with industry, the important concerns are (1) for the inventor of a technology licensed to a company not to direct the trainee to activities that may be of benefit to the interests of the company but are not appropriate for the training and professional development of the trainee; (2) for the trainee to be able to freely communicate the results of the trainee's work; and (3) for the trainee to be able to work in an inventor's laboratory on projects that develop strong professional and academic skills.

The inventor who performs research sponsored by a company that has licensed the technology of the inventor and who also serves as a mentor for trainees must certify in writing to the inventor's department chief and the Director, Research Administration on an annual basis that the trainees under the control of the inventor are either involved in activities independent of the inventor's industrially sponsored research or, if the trainee is funded by the company's research grant, report -the activities that the trainee is performing. The department chief must state in writing that the trainee is involved in research that is an appropriate training assignment, and must send a copy of this report to the Director, Research Administration. Any

issues of conflict will be referred to the Research Executive Committee for action and will be reported to the Executive Committee of the Board of Trustees. The inventor must also agree to submit any confidentiality agreement that the trainee may be asked to sign to the Technology Transfer Office for prior review and approval.

The Hospital will exercise great care to ensure that trainees are not involved in research in ways which could taint the integrity of the research or impede the development or advancement of their careers.

Reporting of research results: The openness of the academic environment is fundamental to the pursuit of new knowledge and advancement of scientific discovery. The academic freedoms of publication and collegial discussion are central to this process and must be preserved. A conflict arises where a company in which the Hospital owns equity seeks greater restrictions on publishing research results than the Hospital generally grants in a typical licensing arrangement. The Hospital's position on reporting research results is that the company will receive a manuscript at the time of submission to a journal or, in the case of a description, abstract or of any public oral presentation, a week in advance. The Hospital's position is that the company may only remove from the manuscript company confidential information, revealed to the Author/inventor as such under the terms of a confidentiality clause in a license or sponsored research agreement. The company has no right to alter or otherwise delay the reporting of the research results. To manage the potential conflict, the Hospital will not agree to any more restrictive terms for reporting research results than those outlined here without specific approval of the Executive Committee of the Board of Trustees.

Disclosure: Institutional ownership of equity holds the potential for undermining public trust in the institution and in the pursuit of scientific knowledge. One mechanism to prevent this potential from materializing is to have full disclosure of the institution's equity holdings. In order to be effective, the disclosure needs to be broad and must reach a varied audience - patients, the research community, and the public at large. Disclosure to the patient population will be addressed through the informed consent process (~ section on Clinical Trials). In addition, the Hospital will include a listing in its annual reports of those companies in which it holds equity as a result of technology transfer arrangements. If timely reporting cannot be accomplished through the annual report, the Hospital will

consider other means of disclosure, such as a press release. Finally, authors of articles concerning research reported by companies in which the Hospital owns equity will be required to disclose the Hospital's financial interest in the research in addition to disclosure of the author's personal interests in the research, if any.

Board membership: A question arises whether the Hospital will compromise its character as an academic teaching Hospital if it participates in the direction of a new company through board membership, exercise of so called "observer rights", or exercise of contractual rights of approval of certain corporate matters. The issues of conflict become more intense if the Hospital holds board seats because the Hospital then has a fiduciary duty to the shareholders that potentially differs from the public interest ordinarily served by the Hospital. Exercise of "observer rights" and contractual rights also raise conflicts, but of a less intense nature. In most cases, the Hospital should be a silent partner and not participate on the board of new companies. One of the most important assets the new company brings to the Hospital is the management team, and the Hospital generally should look to that team and the financial investors who have been selected to support that team. The Hospital ordinarily should not take an active role in managing the company. It is recognized that the new or young company may make decisions about any number of business and scientific issues that may not best serve the Hospital's financial interests and may serve to decrease the value of the technology or may even undermine the development of the technology3. In most cases, this is a risk that the Hospital must assume in order to reduce its exposure to potential conflicts of interest.

Nevertheless, in some cases the primary focus of the new company is to manage the early stage development of a broad-based technology and,. in certain cases, to manage possible cross- licensing and field of use applications. Such a company often serves as a "holding company" for the technology rather than an operating company. Once the technology has been further developed, the company may choose to commercialize the technology itself or may pursue development of the technology through a network of sublicenses. In these cases it may be appropriate

3. The Hospital in its licenses carefully crafts "due diligence" clauses to establish objective development milestones and dates or minimum royalties. The clauses encourage development of the technology, but these clauses, in practice, may be difficult to enforce in order to regain

control of the technology. Generally, the Hospital uses every other means to stimulate the company to aggressively develop the technology. for the Hospital to participate on the board. The Hospital's role on the board of such a holding company is much the same as its role in the licensing of any technology through the Technology Transfer Office: primarily to assure that the technology is developed appropriately to serve the public good. As the company builds value and as new funding is raised to develop products, the founder's share of equity decreases. When the company becomes an operating company, 0+ when the Hospital's share in the company reduces to 10% or less, the Hospital may wish to relinquish its board membership for the reasons noted above.

The Executive Committee of the Board of Trustees must approve any direct participation on the board of a company.

Multiple licenses to a com an in which Children's owns licensed based equity: One of the conflicts that arises in owning equity in a new company is that the Hospital has an incentive to license related technology to such a company. While often this tendency is desirable, the conflict arises in those technologies where the technology may be best developed or the public interest may best be served by licensing it to a large company or even a competitor or perhaps by licensing non-exclusively to many companies. To assure that the Hospital not license its technologies preferentially to a new or young company in which it owns equity, any additional license to such a company must be specifically reviewed and approved by the Executive Committee of the Board. The exception to this policy shall be any technology which is dominated by the claims of a previously licensed patent or which is discovered in a program of research sponsored-by the company in which the Hospital owns equity.

Oversight and Monitoring: As discussed earlier, once a decision is made in a particular case to take equity, the Hospital is committed to oversight and monitoring of the ensuing relationship. This function may be undertaken by the Executive Committee of the Board, or the Executive Committee may designate a Review Committee to carry out this function. In either case, the oversight and monitoring will involve upholding key aspects of these guidelines and any special conditions imposed by the Executive Committee.

RESOLUTION OF ISSUES CONCERNING THE OWNERSHIP OF EQUITY:

In the course or managing institutional equity ownership, unforeseen issues, questions, and allegations of unacceptable behavior inevitably will arise. The Hospital is committed to the thorough investigation and resolution of all serious grievances and allegations relating to or arising from the Hospital's ownership of equity. All such grievances and allegations will be reported to the Executive Committee of the Board of Trustees which will be responsible for overseeing any investigation. To the extent appropriate, the Hospital will inform the Office of the Dean of Harvard Medical School and will share any findings publicly.

Approved by Board of Trustees June 15, 1993